

NOT FOR PUBLICATION

(Doc. No. 288)

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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SCIELE PHARMA INC.,  
(N/K/A SHIONOGI PHARMA INC.),  
ANDRX CORPORATION,  
ANDRX PHARMACEUTICALS, INC.  
(N/K/A WATSON LABORATORIES,  
INC., FLORIDA),  
ANDRX PHARMACEUTICALS, L.L.C.,  
ANDRX LABORATORIES (NJ), INC.  
ANDRX EU LTD.,  
and ANDRX LABS, L.L.C.,

Plaintiffs,

v.

LUPIN LTD.,  
and LUPIN PHARMACEUTICALS, INC.,  
  
and MYLAN INC.,  
and MYLAN PHARMACEUTICALS, INC.

Defendants.

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Civil No. 09-0037 (RBK/JS)

**OPINION**

**KUGLER**, United States District Judge:

This matter comes before the Court upon the motion of Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Defendant” or “Lupin”),<sup>1</sup> pursuant to Federal Rule of Civil Procedure 62(c), to stay this Court’s Order of a Preliminary Injunction issued on December 6, 2011, or, in the alternative, to modify enforcement of the Preliminary Injunction Order. Because the Court finds that Defendant has not made the requisite showing for a stay or modification of the injunction, Defendant’s motion is denied.

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<sup>1</sup> Although the Mylan parties are also defendants in this case, the current motion is brought only by the Lupin defendants.

## **I. BACKGROUND**

Because the facts underlying this case are established in detail in the Opinion accompanying this Court's Preliminary Injunction Order and in its claim construction Opinion, the Court recites only the facts relevant to the procedural posture of this motion. See Sciele Pharma, Inc. v. Lupin Ltd., 09-cv-37 D.I. 279, 2011 U.S. Dist. LEXIS 139892 (D. Del. Dec. 6, 2011) ("Prelim. Injunction Op."); D.I. 191, 2011 U.S. Dist. LEXIS 105572 (D. Del. Sept. 15, 2011) ("Markman Op.>").

Shionogi Pharma Inc. ("Plaintiff") and the Andrx parties captioned above<sup>2</sup> brought this action against Lupin, alleging that Defendant's generic drug infringes patents owned by plaintiffs that are embodied in plaintiffs' Fortamet® drug. A claim construction hearing was held on September 7, 2011, and this Court entered its claim construction Order on September 15, 2011. See Markman Op. On September 30, 2011, Defendant undertook an "at-risk" launch of its generic product, and Plaintiff filed a motion for Preliminary Injunction on October 12, 2011. At the request of the parties, a standstill order was issued and renewed until this Court's Order granting a Preliminary Injunction was entered on December 6, 2011. Pursuant to the Order, Plaintiff filed the requisite bond on December 12, 2011. D.I. 287.

Defendant filed a Notice of Appeal to the Court of Appeals for the Federal Circuit on December 13, 2011. On the same day, Defendant filed a motion to stay this Court's Preliminary Injunction Order pending the Federal Circuit's review, or, in the alternative, to modify enforcement of the Preliminary Injunction Order. D.I. 288. Plaintiff timely responded, D.I. 293, and Defendant submitted a reply, D.I. 297.

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<sup>2</sup> Only the Shionogi plaintiff moved for the underlying Preliminary Injunction Order; accordingly, the current motion is opposed only by the Shionogi plaintiff.

## **II. STANDARD**

Federal Rule of Civil Procedure 62(c) provides, in relevant part, that “[w]hile an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms . . . .” Fed. R. Civ. P. 62(c). Courts must apply a four-factor test in deciding whether or not a stay is warranted:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776 (1987). Moreover, “in the context of preliminary injunctions,” the Federal Circuit has “adopted a flexible approach in analyzing the four factors.” Standard Havens Prods. v. Gencor Indus., 897 F.2d 511, 513 (Fed. Cir. 1990).

## **III. DISCUSSION**

### **A. Defendant Is Not Likely to Succeed on the Merits in Its Appeal**

Defendant is not likely to succeed in its appeal on the issue of the invalidity of Plaintiff’s patent. First, as this Court explained in its Preliminary Injunction Opinion, although there appears to have been confusion at the Patent and Trademark Office concerning the prosecution of Plaintiff’s patent, the claims of the issued ‘866 patent that Defendant contests were, indeed, approved by the PTO. See Prelim. Injunction Op. at 12. Thus, Defendant did not raise a substantial question that it would be able to overcome at trial, by clear and convincing evidence, the presumption of validity protecting Plaintiff’s patent. See Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001) (indicating that, for a party challenging a motion for preliminary injunction to succeed, it must raise a substantial question as to infringement or validity). Cf. Microsoft Corp. v. i4i Ltd. P’ship, 131 S. Ct. 2238, 2242 (U.S.

2011) (“We consider whether § 282 [of the Patent Act of 1952] requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.”); AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1056 (Fed. Cir. 2010) (finding no clear error in district court’s holding that “at trial [the nonmoving party] will likely not be able to demonstrate [invalidity] by clear and convincing evidence . . .”).

Moreover, Defendant’s argument concerning obviousness relied on prior art that had been considered by the PTO during the patent’s prosecution. See Pl. Reply Br. in Support of Prelim. Injunction Motion, 13. Thus Lupin failed to raise a substantial question that its obviousness argument is likely to show at trial, by clear and convincing evidence, that Plaintiff’s patent is invalid.

Because Lupin’s argument regarding its FDA-approved label is identical to the argument it presented to this Court when opposing Plaintiff’s motion for preliminary injunction, the Court merely reiterates the reasoning of its Preliminary Injunction Opinion, and finds that Lupin has not shown that it is likely to succeed in its appeal on noninfringement grounds. Prelim. Inj. Op. at 10-11. The Declaration of Leslie Sands that Defendant has appended to its instant motion does indicate that Lupin is unable to modify its FDA-approved package insert now, based on the results of tests that are different from the tests referenced on the original package insert. Sands Decl. at ¶¶ 5-6. However, this does not alter the fact that, if Lupin submitted “the same tests as the test on the label which measured the mean  $T_{max}$ ,” it would “be permissible for Lupin to substitute its own test results for those of the brand product on the label.” Id. at ¶ 6. Moreover, this does not eliminate the possibility that Lupin could have performed on its own product the same tests as those performed on the brand-name product, and submitted those results to the FDA in the first place.

Finally, Defendant argues that it is likely to succeed on appeal because the recently decided case of Warner Chilcott Laboratories v. Mylan Pharmaceuticals underscores the proposition that district courts must hold an evidentiary hearing to resolve factual disputes at the preliminary injunction stage. 2011 U.S. App. LEXIS 24602 (Fed. Cir. Dec. 12, 2011). At no point did Defendant request an evidentiary hearing. Moreover, in a telephone conference with the parties on October 20, 2011, the Court suggested an evidentiary hearing in which both parties would have the opportunity to present expert testimony and other evidence, asking, “How do you foresee you’re going to proceed on this motion? Are you going to present evidence in court and testimony?” Telephone Conference, Oct. 20, 2011. Both parties waived the opportunity for such an evidentiary hearing, and each agreed that it would prefer to proceed by oral argument. The Court specifically indicated, “I will entertain any evidence any way you want to present [it] to the court.” Lupin’s counsel responded, “[a]t the moment, we probably would be happy to rely on our papers and oral argument.” Telephone Conference, Oct. 20, 2011. Although Defendant indicated that it might reconsider, depending on what was represented in Plaintiff’s papers, Defendant did not express at any later point that it would prefer an evidentiary hearing.

Lupin now argues that it was deprived of the hearing that it did not request, and in fact told the Court it did not want.<sup>3</sup> Going yet one step further, Defendant argues that that, at oral argument, its “presentation [was] truncated to allow the Court to resume a hearing in an ongoing complex criminal matter.” Def. Reply Br. 7. The Court notes that, at the oral argument, Lupin presented no evidence or argument, nor indicated that it would like to present any evidence or argument, that was not contained in its opposition papers and in the volumes of expert

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<sup>3</sup> With respect to defense counsel’s argument that the Court denied Lupin an evidentiary hearing, and its particularly offensive statement that the Court truncated its attention to this matter in favor of other cases on its docket, the Court would remind counsel of the Delaware Lawyers’ Rule of Professional Conduct 3.3(a), whose requirement of candor toward the tribunal inveighs against presenting such sanctionable misrepresentations in this Court, as well as the Federal Circuit.

declarations appended thereto. The Court had perused these documents at length in advance of the hearing, and makes abundant reference to them in its Preliminary Injunction Opinion. Moreover, at oral argument, Lupin was afforded ample time to present those issues for which the Court required clarification. Thus the Court does not find that Lupin is likely to succeed on the merits of its appeal.

**B. Appellant Has Not Made a Showing of Irreparable Harm in the Absence of a Stay**

Because the Court finds that Lupin has not succeeded on the likelihood of success prong, Lupin would need to make a stronger showing of irreparable harm to succeed on this motion. See Standard Havens Prods. v. Gencor Indus., 897 F.2d 511, 513 (Fed. Cir. 1990) (In a motion to stay an injunction pending appeal, “[w]here likelihood of success is less forceful a movant would have to make a stronger showing of irreparable harm in order to tip the balance of equity in his favor.” (internal quotations and citations omitted)). It has not done so. Lupin indicates that the most significant harm it may suffer is that Watson may launch its own generic product. However, over three months have passed since Defendant undertook its launch, and Watson has not launched its product. Therefore, in addition to being a foreseeable consequence of Lupin’s launch, the expectation that Watson will launch remains on the level of speculation. Furthermore, although Defendant presents evidence that its stock price dropped as a result of this Court’s Preliminary Injunction Order, this harm is not sufficient to overcome the fact that Lupin has not shown a likelihood of success on the merits of its appeal, and accordingly a stay or modification of the Preliminary Injunction Order is not warranted.

**C. Other Parties Will Be Substantially Injured by a Stay**

This Court issued its Preliminary Injunction Order in large part because it found that Plaintiff had shown irreparable harm. If a stay is granted and Lupin’s launch of its generic

product is allowed to continue, Shionogi will suffer precisely those harms identified in the Court's Preliminary Injunction Opinion. See Prelim. Injunction Op. at 13-18. The Court finds that these harms constitute substantial injury.

**D. The Public Interest Does Not Favor a Stay of the Preliminary Injunction Order**

In granting the Preliminary Injunction Order, this Court found that the public interest factor was neutral, since the enforcement of patent rights and the production of low-cost generic drugs are both significant interests at stake in this matter. Prelim. Injunction Op. at 20. Defendant presents no new argument on this prong in its Rule 62(c) motion. Def. Br. in Support of Stay, 20. The Court maintains its holding that this factor is neutral.

**E. Modification of the Issued Preliminary Injunction Order Is Not Warranted**

In support of its argument that this Court should modify its Preliminary Injunction Order to provide that the injunction will be lifted if another generic version of Fortamet® enters the market, Lupin argues only that "there is no reason not to modify the injunction in the event of an authorized generic launch." Def. Reply Br. in Support of Motion to Stay, 7. The Court finds that the absence of a reason to deny equitable relief does not qualify as a reason for granting it.

**IV. CONCLUSION**

For the foregoing reasons, the Court finds that Defendant has not satisfied the four-factor test for a stay or modification of an injunction, pursuant to Federal Rule of Civil Procedure 62(c). Accordingly, Defendant's motion is **DENIED**.

Dated: 1/12/2012

/s/ Robert B. Kugler  
ROBERT B. KUGLER  
United States District Judge